IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE RANBAXY GENERIC DRUG APPLICATION ANTITRUST LITIGATION	MDL No. 10-md-02878-NMG

NONPARTY ASTRAZENECA PHARMACEUTICALS LP'S MEMORANDUM IN SUPPORT OF MOTION TO RECONSIDER DEFENDANTS RANBAXY, INC. AND SUN PHARMACEUTICAL INDUSTRIES LTD.'S MOTION TO COMPEL THE PRODUCTION OF DOCUMENTS

AstraZeneca Pharmaceuticals LP ("AstraZeneca") submits this memorandum in support of its motion for the Court to reconsider its decision allowing Defendants Ranbaxy, Inc.'s, and Sun Pharmaceuticals Industries Ltd.'s ("Defendants") motion to compel (the "Motion") (ECF No. 256), in connection with the third-party subpoena served by Defendants on AstraZeneca on July 31, 2019 (the "Subpoena"). AstraZeneca is a nonparty to the above-captioned litigation (the "Action") and has no interest in the subject matter or outcome of the Action. Nonetheless, AstraZeneca has engaged with Defendants to limit the scope of the Subpoena, produced thousands of pages of responsive data and other documents, and agreed to produce all of the data required for Defendants accomplish their stated purpose: "to determine whether members of the proposed class actually suffered injuries in the form of the alleged overcharges and whether any damages can be measured using common evidence." (ECF No. 257, pp. 5-6.)

As described below, AstraZeneca cannot feasibly produce Medicaid rebate data—which is not relevant to the prices paid by members of the putative classes in this action—on the timeline set by the Court. Accordingly, AstraZeneca asks the Court to reconsider its order that AstraZeneca produce this data by December 10. In addition, AstraZeneca asks the Court, as required by Rule 45, to order Defendants to reimburse AstraZeneca for its costs incurred in producing the data ordered by the Court in response to Defendants' motion to compel (ECF No. 256).

BACKGROUND

On July 31, 2019, Defendants served the Subpoena on AstraZeneca. In relevant part, the Subpoena sought AstraZeneca's "United States transactional sales data for Nexium and any Nexium Authorized Generic from January 2005 to the present, including documents reflecting the products sold, the sale dates, the customer names, the amounts sold, the prices charged, and all applicable rebates, allowances, offsets, chargebacks, or documents relating to the sales." (*See* ECF No. 267-2. p. 9 (Request 1).)

On September 3, 2019, AstraZeneca objected to the requests in the Subpoena, including the relevant request for Nexium sales transaction data, on the basis that compliance would be unduly burdensome and would require AstraZeneca to create documents that do not already exist. *Id.* Specifically, AstraZeneca objected that "this Request seeks nearly 14 years' worth of voluminous and highly granular transactional sales data, which would require extensive, time-consuming, and costly efforts by AstraZeneca to locate, collect, and produce the requested documents." *Id.* pp. 10-12.

The parties met and conferred extensively over the course of the following year in an effort to narrow the requests and produce the data necessary for Defendants' purposes. As a result of these discussions, and in a good faith attempt to address the requests in Defendants' Subpoena, AstraZeneca has made nine productions in response to the Subpoena: in November 2019, January 2020, February 2020, June 2020, September 2020, October 2020, and November 2020. These productions total more than 2,500 pages of data and other documents, including invoice-level Nexium sales and rebate data for the period from January 2012 through December 2019. In addition, AstraZeneca has committed to producing chargeback data for relevant Nexium products during the same period.

On November 12, this Court granted Defendants' motion to compel and ordered AstraZeneca to produce two additional categories of data: (1) data reflecting the fees that AstraZeneca paid to certain wholesalers and group purchasing organizations as compensation for administrative services related to product distribution; and (2) data relating to rebates paid directly to various States under the Medicaid program. In the same order, the Court ordered the parties to continue negotiating the relevant data to limit the burden on AstraZeneca, and granted AstraZeneca

leave to file a motion no later than November 30 "setting out particular reasons why the production is unduly burdensome." (ECF No. 298.)

ARGUMENT

I. Rule 45 Requires the Court to Protect Third Parties From Undue Burden.

Federal Rule of Civil Procedure 26(b)(1) expressly limits the permissible scope of discovery to "matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering . . . [*inter alia*], the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit."

With respect to third party subpoenas, Federal Rule of Civil Procedure 45 further emphasizes these limits on discovery and requires that a "party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to a subpoena. The court [] must enforce this duty and impose and appropriate sanction . . . on a party or attorney who fails to comply." Fed. R. Civ. P. 45(d)(1). Rule 45 also requires the court to protect non-party subpoena recipients from undue burden. Fed. R. Civ. P. 45(d)(3)(A)(iv); *see also* Fed. R. Civ. P. 1 (the Fed Rules "should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding.")

Rule 45 provides particular protections for recipients of subpoenas that seek production of electronically stored information. "The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost." Fed. R. Civ. P. 45(e)(1)(D). On a motion to compel discovery or for a protective order, if the subpoena recipient shows that the information is not reasonably accessible, the court can only order discovery upon a showing of good cause by the requesting party. *See id.*

Further, Rule 45 requires the court to shift costs when a non-party incurs significant expense from compliance with a subpoena. *See* Fed. R. Civ. P. 45(d)(2)(B)(ii); *see also Koopman v. Robert Bosch, LLC*, 2018 WL 9917679, *1 (S.D.N.Y. May 25, 2018) (requiring the non-party to bear some expenses after considering the equities); *see also Behrend v. Comcast Corp.*, 248 F.R.D. 84, 86 (D. Mass. 2008) (allocating costs under a prior version of Rule 45 and considering three factors: "(1) whether the non-party actually has an interest in the outcome of the case, (2) whether the non-party can more readily bear the costs than the requesting party, and (3) whether the litigation is of public importance.").

II. AstraZeneca Cannot Practicably Collect and Produce the Requested Data.

AstraZeneca cannot practicably comply with the Court's order to produce Medicaid rebate data for the period 2012 through 2019 by December 10. There is no quick or simple way to collect all of the requested data, which is stored in multiple locations that are either (1) already being heavily burdened by routine, business-critical activities; and/or (2) are incapable of routinely generating the types of reports requested by Defendants and therefore require significant manual processing and oversight.

The requested data for the period from the beginning of 2017 to present is stored in AstraZeneca's end-to-end revenue management database. November 30, 2020 Declaration of Charles Fidler (Fidler Decl.), ¶ 5. AstraZeneca uses this database to manage many aspects of its business, including to maintain and track information about its financial agreements with customers and other entities, to realize revenue that it generates under those agreements, and to trigger payments required by those agreements. *Id.* ¶ 2. In addition, the team that is responsible for maintaining the database uses it to make information available in real-time to AstraZeneca's independent auditors, as well as to perform financial testing and monitoring, and to produce information that is disseminated throughout AstraZeneca in support of more than 60 Sarbanes-

Oxley internal controls. *Id.* ¶ 3. In other words, this database is crucial to maintaining AstraZeneca's operations in the United States and around the world, and to meeting a number of regulatory obligations. Further complicating matters, the database is currently undergoing a long-planned upgrade. *Id.* ¶ 4.

The requested data for the period from 2005 through 2016 is stored in a predecessor to the current database described above. *Id.* ¶ 6. This legacy database has been archived, and AstraZeneca's businesspeople do not maintain a user interface that would allow them to collect or review the data stored in it. *Id.* Further, transaction-level sales data is not maintained in the format requested by the Defendants, or in any format that would be readily usable by them. In fact, because the database architecture is different from AstraZeneca's current database, the data must be compiled and **manually reviewed** for accuracy before it can be relied upon by AstraZeneca's own employees—a process of collection and confirmation that requires a great deal of work and must be repeated numerous times to ensure accuracy. *Id.* ¶ 7.

In both relevant databases, collecting data for rebates under the Medicaid program is particularly burdensome. Data relating to these Medicaid rebate transactions are stored in different parts of the databases, referred to as "tables," and each addition of a table to a database search multiplies the total number of data entries that must be collated and reconciled. *Id.* In order to collect the requested Medicaid rebate data, AstraZeneca must conduct queries in tables that are stored separately from the other data produced in this matter (*i.e.*, direct sales, other types of rebates, chargebacks, and administrative fees). As a result, in order to collect and produce this data, AstraZeneca is required to construct queries in these additional tables, perform an entirely new process of testing and refining these queries that does not rely on data that overlaps with the process for producing the other data in this matter, and then conduct a manual review of this data

for accuracy, which would require a labor-intensive process spanning weeks or even months. *Id.* ¶¶ 8-9.

AstraZeneca has limited personnel with the knowledge and capabilities to perform these additional searches. *Id.* As described above, these personnel have significant responsibilities that are central to AstraZeneca's business operations, its compliance and risk management functions, and its legally-mandated reporting obligations. *Id.* ¶¶ 2-3. In addition to their standard responsibilities, this personnel have prioritized the production of the other data which it has committed to produce in this matter, including the chargeback data agreed by the parties and the administrative fee data ordered by the Court. *Id.* ¶ 10. Despite their best efforts, this personnel have been unable to keep pace with all of these competing priorities, and cannot feasibly complete the production of the Medicaid rebate data before January 15, 2021. *Id.* ¶ 11.

Moreover, as was explained by AstraZenca in prior briefing the requested data is not in any way probative of the volume of Nexium sales to members of the putative classes in this action, or the prices they paid. (*See* ECF No. 293). The States that received the relevant Medicaid rebates are not members of these classes, i*d.*, as Defendants conceded at the November 12 hearing. Further, contrary to Defendants' argument, this data will not provide any additional information about States' purchases through members of the putative classes that will not already be captured in the direct sales, rebate, and chargeback data that AstraZeneca has already produced or committed to produce, which will reflect all sales to class members. *Id.* Defendants have not put forth any non-speculative argument to the contrary. Accordingly, the requested data is not "relevant to any party's claim or defense," is "[dis]proportional to the needs of the case," and "the importance of the discovery in resolving the issues and . . . the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1).

CONCLUSION

In conclusion, AstraZeneca asks the Court to reconsider its order that AstraZeneca produce the requested administrative fee and Medicaid chargeback data by December 10, 2020.

Dated: November 30, 2020

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing document was served by ECF on all parties of record.

Dated: November 30, 2020

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